

REMARKS**I. PRELIMINARY REMARKS**

Minor amendments have been made to the specification. No claims have been amended, added or canceled. Claims 10-37 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Submitted herewith are proposed drawing corrections marked in red. Upon approval, formal drawings incorporating such corrections will be submitted in accordance with the procedures set forth in PTO form 948.

II. DOUBLE PATENTING REJECTION

Claims 10-12, 16-22, 27, 30 and 32-37 have been rejected under the judicially created doctrine of obviousness-type double patenting. Applicant respectfully submits that the obviousness-type double patenting rejection has been obviated by the Terminal Disclaimer attached hereto.¹

III. FORMALISTIC OBJECTIONS TO THE DRAWINGS AND SPECIFICATION

The drawings and specification have been objected to because of a number of minor informalities. Applicant respectfully submits that such informalities have been obviated by the proposed amendments to the drawings and the amendments above to specification.

¹ Applicant notes for the record that the filing of a Terminal Disclaimer serves only to remove the obviousness-type double patenting rejection and raises neither a presumption, nor an estoppel, with respect to the merits of the rejection. See *Quad Environmental Technologies v. Union Sanitation District*, 20 USPQ2d 1393, 1394-95 (Fed. Cir. 1991).

IV. BRIEF DESCRIPTION OF CERTAIN ILLUSTRATED EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to catheter assemblies. As illustrated for example in Figure 42, a formal version of which is reproduced below for the Examiner's convenience, a catheter probe 404 in accordance with one embodiment of a present invention includes a catheter 12, a handle 18 with a **strain relief element 21**, and a pull wire 60 with a proximal portion that extends along the exterior of the catheter 12. The pull wire 60 may be secured to the handle 18. In the exemplary embodiment illustrated in Figure 42, the pull wire 60 is secured to the handle's strain relief element 21 with an anchoring element 406.

FIG. 42

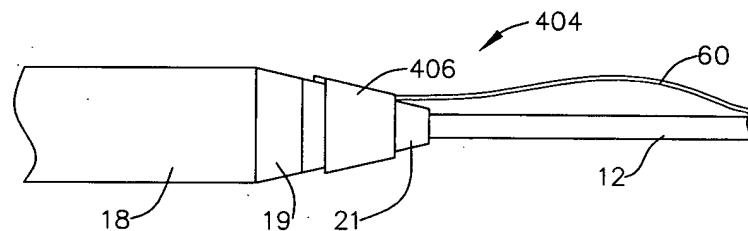


Figure 42 of the Present Application

Another exemplary embodiment of a present invention is generally represented by reference numeral 420 in Figure 44, a formal version of which is reproduced below for the Examiner's convenience. Here, a gripping mechanism 422 is provided in spaced relation to the handle 18. The gripping mechanism 422 holds the proximal portion of the pull wire 60 relative to the catheter 12.

FIG. 44

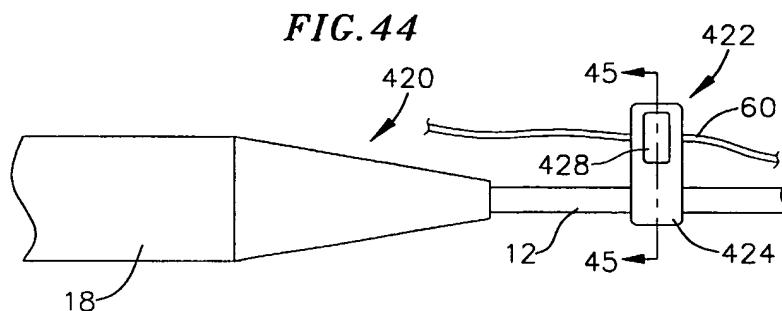


Figure 44 of the Present Application

V. PRIOR ART REJECTIONS

A. The Rejections

Claims 10-12, 15-23 and 27-37 have been rejected under 35 U.S.C. § 102 as being anticipated by the Whayne patent (US 6,071,279). Claims 13 and 24-26 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Whayne patent (US 6,071,279) and the Brennen patent (US 5,439,006). The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. Discussion Specifically Concerning Claims 10-21

Independent claim 10 calls for a combination of elements comprising “a handle including a handle body and a ***strain relief element***,” “an elongate catheter body” and “a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the ***exterior surface*** of the catheter body and secured to the strain relief element.”

With respect to the rejection under U.S.C. § 102, applicant respectfully submits that the Whayne patent fails teach or even remotely suggest a number of elements in the combination defined by independent claim 10. For example, the Whayne patent fails to teach or even remotely suggest the use of a “strain relief element.” The text of the Whayne patent does not even include the word “strain” or the word “relief.” The Office Action has apparently taken the position that element 68 in Figure 1 of the Whayne patent corresponds to the claimed “strain relief element.” As clearly described in column 11, lines 45-57 of the Whayne patent, element 68 is a ***steering mechanism*** that is used to pull steering wires in the Whayne catheter. Applicant respectfully submits that a

steering mechanism simply is not a “strain relief element,” as this term would be understood by one of ordinary skill in the art who has reviewed the present application.²

The Whayne patent also fails to teach or suggest “a control element defining ... a *proximal portion* extending along the **exterior** surface of the catheter body and secured to the strain relief element.” The Office Action appears to have taken the position that element 152 (as illustrated in Figures 21-24 and described in column 16, lines 16-18 of the Whayne patent) corresponds to this aspect of the claimed combination. The Whayne patent specifically states that “***the catheter tube 12 includes an interior lumen 156, which accommodates sliding passage of the pull wire 152.***” [Column 16, lines 14-16, emphasis added.] As such, and in contrast to the combination defined by independent claim 10, the proximal portion of the Whayne pull wire 152 clearly does not extend along the exterior surface of the catheter tube 12.

As the Whayne patent fails to teach or suggest each and every element of the combination recited in independent claim 10, applicant respectfully submits that claims 10-12 and 15-21 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

Turning to the rejection of dependent claim 13 under 35 U.S.C. § 103, the Brennen patent discloses a steerable device including a tubular member 10, a pull wire 12 and a handle 28. Applicant respectfully submits that the Brennen patent fails to remedy the deficiencies in the Whayne patent described above with respect to independent claim 10. For example, the Brennen patent does not teach or suggest the use of a “strain relief element” or “a control element defining ... a *proximal portion* extending along the **exterior** surface of the catheter body and secured to the strain relief element.” The Office Action appears to have taken the position that element 34 in the Brennen patent corresponds to the claimed strain relief element. As discussed in column 7, lines 16-49, element 34 is a pivotable lever that is used to pull the pull wire 12. Such a lever simply is not a “strain relief element,” as this term would be understood by one of

² “Claims in an application are to be given their broadest reasonable interpretation ***consistent with the specification*** [and] claim language should be read in light of the

ordinary skill in the art who has reviewed the present application. Additionally, the proximal portion of the Brennen pull wire 12 is clearly located **on the inside** of the tubular member 10.

As the Whayne and Brennen patents fail to teach or suggest the combination of elements recited in claim 13 (which by definition includes the combination of elements recited in independent claim 10), applicant respectfully submits that the rejection of claim 13 under 35 U.S.C. § 103 is improper and must be withdrawn.

C. Discussion Specifically Concerning Claims 22-37

Independent claim 22 calls for a combination of elements comprising "a handle," "an elongate catheter body," "a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the **exterior** surface of the catheter body" and "an apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body."

With respect to the rejection under U.S.C. § 102, applicant respectfully submits that the Whayne patent fails teach or even remotely suggest a number of elements in the combination defined by independent claim 10. For example, and as described in detail in Section V-B above, the Whayne patent fails to teach or suggest a combination of elements including "a control element defining ... a **proximal portion** extending along the **exterior** surface of the catheter body." The Whayne pull wire 152 instead passes through a lumen 156 **within** the catheter tube 12. Additionally, the Office Action appears to have taken the position that element 36 in the Whayne patent corresponds to the claimed "apparatus ... adapted to secure the proximal portion of the control element in predetermined relation to the catheter body." Element 36 is merely a gripping surface for the sheath 26 and is not used to secure anything to the catheter tube 12.

specification as it would be interpreted by one of ordinary skill in the art." *In re Young and Sneed*, 218 USPQ 384, 388 (Fed. Cir. 1983) [Emphasis added.]

As the Whayne patent fails to teach or suggest each and every element of the combination recited in independent claim 22, applicant respectfully submits that claims 22, 23 and 27-37 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

Turning to the rejection of claims 24-26 under 35 U.S.C. § 103, applicant respectfully submits that the Brennen patent fails to remedy the deficiencies in the Whayne patent described above with respect to independent claim 22. For example, the Brennen patent does not teach or suggest the use of a control element with a proximal portion extending along the **exterior** surface of the catheter body. The proximal portion of the Brennen pull wire 12 is clearly located **within** the tubular member 10. The Brennen patent also fails to teach or suggest an apparatus, located in spaced relation to the handle 28, that secures the **proximal portion** of the pull wire 12 to the tubular member 10.

As the Whayne and Brennen patents fail to teach or suggest the respective combinations of elements recited in claims 24-26 (which by definition include the combination of elements recited in independent claim 22), applicant respectfully submits that the rejection of claims 24-26 under 35 U.S.C. § 103 is improper and must be withdrawn.

VI. CLOSING REMARKS

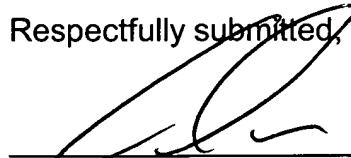
In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

3/21/02
Date

Respectfully submitted,



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**VERSION OF AMENDMENTS TO APPLICATION WITH
MARKINGS TO SHOW CHANGES MADE**

***On page 1 of the specification, the paragraph on lines 2-4 has been
amended as follows:***

This application is a continuation of co-pending U.S. application Serial No. 08/961,374, filed October 30, 1997, now U.S. Patent No. 6,203,525, which is itself a continuation-in-part of co-pending U.S. application Serial No. 08/769,856, filed December 19, 1996, now U.S. Patent No. 6,332,880, which is incorporated herein by reference thereto.

***On page 6 of the specification, the paragraph of lines 25 and 26 has been
amended as follows:***

Fig. [26] 26A is a side view of another embodiment of a catheter end tip protective plug;

***On page 6 of the specification, the paragraph of lines 27 and 28 (prior to
the present amendment) has been amended as follows:***

Fig. 27 is a side cut away view of the catheter end tip with [the] another
embodiment of a protective plug [shown in Fig. 26];